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FDA Ruling Update

Federal Judge Osteen's decision last Friday on challenges to the FDA authority to regulate tobacco, in some respects "muddied the water" on what the future holds for FDA enforcement and industry compliance.

In his 65 page decision the judge ruled ~

- The February 28th FDA rules setting a federal minimum age of 18 to buy tobacco products and requiring retailers to ask for photo ID's of those under 27, are within the scope of FDA authority. These two rules remain in effect.

- The FDA has the authority to regulate cigarettes and smokeless tobacco products as "drugs" or "medical devices" if the FDA's claims are sustained. Should the Judge's decision be upheld on appeal a separate trial will be necessary to determine whether the FDA can prove its assertions.

- The FDA does not have the authority under the Food, Drug and Cosmetic Act to regulate tobacco product advertising and promotion. Thus all FDA rules pertaining to advertising (magazines, outdoor, in-store, etc...) and other promotion (giveaways, event sponsorship, etc...) have been held to be invalid. The government is appealing this portion of the Judge's decision.

- The FDA's regulations regarding access (vending machines, self-service displays, etc...) and labeling requirements are within the scope of their authority. However, the FDA must in separate proceedings, prove those restrictions are valid, if this aspect of the Judge's decision is upheld on appeal.

- A "stay" order has been issued on all FDA regulations set to go into effect on August 28th. This means all FDA regulations, except the two which took affect on February 28th are enjoined from being enforced until the stay order is lifted by Judge Osteen or the Appeals Court. Please note, even though Judge Osteen has stated the FDA has grounds for regulating access issues, he has enjoined them from implementing the regulations pertaining to self-service displays, vending machines, and others.

Both the FDA and industry have indicated they will appeal portions of Judge Osteen's ruling to the Federal District Court in Richmond. This process is expected to take a minimum of six months.

The bottom line: A number of issues remain to be resolved by the courts. A process which will likely take several months. In the mean time no additional FDA regulations will go into effect.

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